FORM PTO-1082

CASE DOCKET NO. 17720-059

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
DATE: June 11, 1999

Transmitted herewith for filing is the patent application of
Inventor(s): Robert F. Baugh, Carole G. Lane and Adrian C. Wilson
For: Test Cartridge For Evaluating Blood Platelet Functionality
Enclosed are:

X Three (3) Sheets of drawings (Figures 1-3).
X An Assignment of the invention to Medtronic, Inc.
X Copy of parent Declaration for Patent Application.
X Copies of the parent Intervention by Assignee, Revocation of Power of Attorney and Appointment of New Power of Attorney, with Certificate Under 37 C.F.R. § 3.73(b).
__ Verified Statements to establish small entity status under 37 CFR 1.9 and 37 CFR 1.27, Independent Inventor and Small Business Concern.

The filing fee has been calculated as shown below:

	(Col. 1)	(Col. 2)	SMALL ENTITY		OR	Other than a SMALL ENTITY	
FOR:	NO. FILED	NO. EXTRA	RATE	FEE		RATE	FEE
BASIC FEE	XXXXXXX	XXXXXXXX	XXXX	$ 380		XXXX	$ 760
TOTAL CLAIMS	5 - 20 =	0	X $9	$___		X $18	$ 0
INDEP CLAIMS	2 - 3 =	0	X $39	$___		X $78	$___
__ MULTIPLE DEPENDENT CLAIM PRESENTED			X $130	$___		X $270	$___
			TOTAL	$___	OR	TOTAL	$ 760

__ Please charge my Deposit Account No. _____ the amount of $_____. A duplicate copy of this sheet is enclosed.
X A check in the amount of $760.00 to cover the filing fee is enclosed.
__ A check in the amount of $_____ to cover assignment recordal fee is enclosed.
X The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 03-1725 . A duplicate copy of this sheet is enclosed.
  X Any additional filing fees required under 37 CFR 1.16.
  X Any patent application processing fees under 37 CFR 1.17.
X The Commissioner is hereby authorized to charge payment of the following fees during the pendency of this application or credit any overpayment to Deposit Account No. 03-1725 . A duplicate copy of this sheet is enclosed.
  X Any patent application processing fees under 37 CFR 1.17.
  X The issue fee set in 37 CFR 1.18 at or before mailing of the Notice of Allowance, pursuant to 37 CFR 1.311(b).
  X Any filing fees under 37 CFR 1.16 for presentation of extra claims.

Respectfully submitted,

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June 11, 1999

Via Express Mail No. EM590190216US

Assistant Commissioner for Patents
BOX PATENT APPLICATION
Washington, DC 20231

Re: DIV U.S. Pat App: TEST CARTRIDGE FOR EVALUATING BLOOD PLATELET FUNCTIONALITY

Inventors: Robert F. Baugh, Carole G. Lane, and Adrian C. Wilson, filed concurrently herewith, a division of Serial No. 08/640,275, filed April 30, 1996

Atty File No.: 17720-059 (DIV) / Medtronic Ref. No.: P3092.01

Sir:

This is a request for filing a divisional application under 37 C.F.R. §1.60, of pending prior application number 08/640,275, filed on April 30, 1996, entitled *Test Cartridge for Evaluating Blood Platelet Functionality.*

Enclosed herewith for filing is a complete copy of the above-identified application including nine (9) pages of specification having two (2) pages of claims (1-10), abstract, three (3) sheets of drawings (Figures 1-3), as originally filed, along with copies of the parent Intervention By Assignee, Revocation of Power of Attorney and Appointment of New Power of Attorney, and Certificate Under 37 CFR 3.73(b); Notice of Recordation of Assignment Document, Assignment Recordation form cover sheet, Assignment of Medtronic HemoTec, Inc. to Medtronic, Inc., and Declaration. I hereby verify that the papers are a copy of the latest signed prior application number 08/640,275.

A Preliminary Amendment is enclosed. Please enter this amendment prior to calculating the fee.

MSI

CHRISMAN, BYNUM & JOHNSON, P.C. IS A MEMBER OF MACINTYRE STRATER INTERNATIONAL LIMITED (MSI), A WORLDWIDE ASSOCIATION OF INDEPENDENT LAW AND ACCOUNTING FIRMS WITH TWO HUNDRED MEMBER FIRMS IN SEVENTY-EIGHT COUNTRIES.

Please address all communications relative to this application to the undersigned principal attorney of record at the address and telephone number shown.

Respectfully

Steven C. Petersen

SCP\mac

Enclosures

IN THE UNITED STATES PATENT AND TRADEMARK OFFICES

Applicants:	Robert F. Baugh, Carole G. Lane, Adrian C. Wilson	
Serial No.:	To be assigned	Art Unit: To be assigned
Filing Date:	To be assigned	Examiner: To be assigned
Title:	TEST CARTRIDGE FOR EVALUATING BLOOD PLATELET FUNCTIONALITY	
Atty. Dkt. No.:	17720-059	
Medtronic Ref. No.:	P4455.01	

PRELIMINARY AMENDMENT

To: Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Please enter the following amendment to the above-referenced patent application.

In the Specification:

On page 1, below the title "TEST CARTRIDGE FOR EVALUATING BLOOD PLATELET FUNCTIONALITY" center and insert the heading --CROSS-REFERENCE TO OTHER APPLICATION-- and begin a new paragraph, and insert --This application is a divisional of U.S. Patent Application No. 08/640,275, filed April 30, 1996.--.

In the Claims:

Please cancel claims 1, 2, 3, 7, and 9, without prejudice to the subject matter contained therein.

REMARKS

Applicants believe that all the claims now pending in this patent application, as amended and described above, are now allowable and that all other problems raised by the Examiner have been rectified. Therefore, Applicants respectfully request the Examiner to reconsider her rejections and to grant an early allowance. If any questions or issues remain to be resolved, the Examiner is requested to contact the Applicants' attorney at the telephone number listed below.

DATED: June 11, 1999

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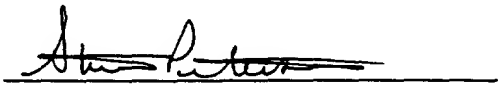
CERTIFICATE OF EXPRESS MAILING UNDER 37 C.F.R. § 1.10

I hereby certify that the foregoing PRELIMINARY AMENDMENT is being deposited with the United states Postal Service as EXPRESS MAIL POST OFFICE TO ADDRESSEE, postage prepaid, EXPRESS MAIL LABEL NO. EM590190216US, in an envelope addressed to: Assistant Commissioner for Patents, BOX PATENT APPLICATION, Washington, DC 20231, on this 11th day of June 1999.

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8

I hereby certify that the attached **INTERVENTION BY ASSIGNEE, REVOCATION OF POWER OF ATTORNEY AND APPOINTMENT OF NEW POWER OF ATTORNEY,** Certificate under 37 C.F.R. 3.73(b); copy of Assignment from inventors to Medtronic HemoTec, Inc; copy of Assignment from Medtronic HemoTec, Inc. to Medtronic, Inc.; and Return Postcard is being deposited with the United States Postal Service, first-class mail, postage prepaid, in an envelope addressed to Assistant Commissioner of Patents and Trademarks, BOX NO FEE, Washington, D.C. 20231, on this 13 day of April, 1997.



SCANNED

TEST CARTRIDGE FOR EVALUATING BLOOD PLATELET FUNCTIONALITY

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to an apparatus for evaluating blood platelet functionality. More specifically, the invention relates to an improved multicell cartridge for use in evaluating blood platelet functionality and method for using the same.

2. Description of the Prior Art

It has been observed that blood platelets play a significant role in the clotting or coagulation of whole blood. When platelets are activated, they shorten the clotting time of the blood. This shortening is related to the initial status of the platelets and platelet disfunction is considered a leading cause of post-surgical bleeding following cardiopulmonary bypass surgery.

Blood platelet functionality is conventionally determined by mixing blood and a clot promoting reagent such as kaolin in a buffer solution. This is done in a series of test cells incorporated in a test cartridge. After adding the clotting reagent, the blood/kaolin solution in each cell is agitated to activate the platelets to promote clotting. The degree of agitation of the blood sample in each cell differs one from the other. As described in U.S. Pat. No. 5,314,826, the clotting time is proportional to the degree of agitation. By comparing clotting times of aliquots of the blood as a function of degree of agitation, the blood platelet functionality can be determined. This process and the apparatus for carrying it out are disclosed in detail in

U.S. Pats. Nos. 4,599,219 and 5,314,826. Where necessary for a further understanding of the present invention, the disclosures in these two patents are incorporated by reference herein.

Chemical platelet activators or reagents are well-known in the art. One such activator, 1-O-alkyl-2-acetyl-sn-glyceryl-3-phosphorylcholine, a biologically active phospholipid, is disclosed in Demopoulos, et al., J. Biol. Chem., 1979; 254:9355-8. This platelet activator or reagent, often referred to as a platelet activating factor, enhances the ability of active platelets to effectively participate in the blood clotting reaction and thereby shorten the clotting time of the blood. If the platelets are inactive or not functioning normally, the activator will have a lessened or no effect on the clotting time.

OBJECTS OF THE INVENTION

It is the principal object of the present invention to provide an improved platelet functionality test cartridge that facilitates the evaluation of functional platelets in a blood sample.

Another object of the present invention is to provide a test cartridge that, upon receipt of blood sample aliquots therein, provides clotting results that are predictive of platelet activity.

SUMMARY OF THE INVENTION

In accordance with the foregoing objects, the present invention is embodied in a cartridge having a plurality of test cells. Each cell is adapted for receiving an aliquot part of a blood sample. A measured amount of clotting reagent is applied in the reaction chamber of each cell as a dried fill. The amount of reagent in each cell differs from the amount of reagent

in each other cell, at least one of the cells containing no platelet activating reagent. Additionally, amounts of heparin or protamine may be added in each cell either as a liquid or dried fill. The cells also include a clotting reagent such as kaolin which on use of the cartridge is inserted into the reaction chamber and mixed with the blood and platelet activation reagent. The relative clotting times of the samples in each of the cells is measured and, when compared to a standard and each other, determines the platelet functionality of the blood sample.

The cartridge and method of determining platelet functionality is useful in connection with open heart and cardiopulmonary surgery wherein the blood condition of the patient must be closely monitored.

DESCRIPTION OF THE DRAWINGS

Fig. 1 is a front elevation view of a multicell cartridge embodying the present invention.

Fig. 2 is a section view taken substantially in the plane of line 2-2 on Fig. 1.

Fig. 3 is a diagram showing the relationship of platelet activating factor concentration to clotting time.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention is embodied in a test cartridge 10 having a plurality of test cells 11, preferably six such cells, depending from and integral with a cartridge plate 12 having a front depending skirt or panel 14. The cartridge is adapted to be inserted into a test apparatus such as shown and described in detail in U.S. Pat. 4,599,219 for the determination of clotting time of an aliquot blood sample inserted into each test cell 11 as described in detail in said patent.

Each cell is formed by a downwardly tapered tube 15 defining an inwardly projecting annular seat 16 intermediate its ends and in turn defining an upper sealing surface 18 and a lower sealing surface 19. A resilient flexible sliding plug 20 is positioned in the lower end of the tube 15 while a plunger 21 defined by a plunger shaft 22 and a sealing washer or disk 24 is positioned in the upper portion of the tube. The sealing washer 24 seats against the upper sealing surface 18 of the annular seat and defines with the plug 20 a lower clotting reagent chamber 25. The tube 15 defines above the washer 24 a blood receiving reaction chamber 26. At its upper end the plunger 21 defines a flag 28 and is adapted for engagement by the test machine (not shown).

A clotting reagent 29, such as kaolin in a buffered, bacteriostatic solution, is contained in the clotting reagent chamber 25 above the plug 20 and below the seal washer 24. When the cartridge is used, the plunger 21 of each cell is lifted and the plug 20 is pushed upwardly, thereby forcing the clotting reagent into the blood sample contained in the upper cell reaction chamber 26 to initiate clotting.

In accordance with the present invention, a measured amount of a chemical platelet activating factor or reagent 30 is provided in the top or upper reaction chamber 26 as a dried fill. This platelet activating factor composition is dissolved in the blood sample when the blood sample is introduced into the clotting chamber 26 and the clotting reagent 29 added and mixed therein. Additionally, selected amounts of heparin or protamine may be utilized as a dried fill in the reaction chamber 26, depending on the chemical procedure to be utilized.

In order to provide a series of differing clotting times, the amount of platelet activating factor in each

cell differs from the amount in each other cell. In the first two cells 11A and 11B (as shown in Fig. 1), no platelet activating factor is utilized. In each succeeding cell 11C, 11D, 11E and 11F, increasing amounts of platelet activating factor or reagent are utilized.

The preferred platelet activating factor is the compound 1-O-alkyl-2-acetyl-sn-glyceryl-3-phosphorylcholine, a biologically active phospholipid. Other factors or compounds which may be used are collagen, epinephrine, ristocetin and arachidonic acid. Fills of the preferred platelet activating factor, 1-O-alkyl-2-acetyl-sn-glyceryl-3-phosphorylcholine, are prepared by mixing the factor with a saline (NaCl) solution containing 0.25% bovine serum albumin, and diluting with deionized water to the desired factor concentrations. An amount of each solution of the desired factor concentration is placed in a cell and allowed to evaporate, leaving a solid or dry fill residue of the desired amount of platelet activating factor. Desired amounts of heparin and protamine may also be added and dried as a fill.

The clotting reagent, such as kaolin, is prepared as a 4% w/v suspension in hydroxyethylpiperazine ethanesulfonic acid buffer with 0.5m calcium chloride, and sodium azide as a bacteriostatic agent. The amount of 0.088ml of this clotting reagent is loaded into the reagent chamber 25 of each cell 11 of the cartridge 10.

In use, aliquots of 0.35ml per cell of a blood sample are dispensed into each cell. This results in platelet activating factor (PAF) blood concentrations illustratively shown in the following Table.

TABLE I

Cartridge PAF Concentrations					
Amount of PAF in Platelet Function--PAF Cartridge					
Cell A	Cell B	Cell C	Cell D	Cell E	Cell F
0.0 ng	0.0 ng	23 ng	116 ng	230 ng	2.76 μg
Final Concentration of PAF in Blood					
0.0 nM	0.0 nM	1.25 nM	6.25 nM	12.5 nM	150 nM

After introducing the blood samples in each cell reaction chamber, the clotting reagent is inserted into each reaction chamber and the clotting time of the blood in each cell is determined. From the clotting time for each cell, the clot ratio is calculated. Clot ratio is the ratio of the clotting times for cells C, D, E and F compared to the average control clotting times, Cells 11A and 11B. Platelet function is expressed as a percentage of the maximum clot ratio response observed in a normal population. This value of a normal population response is known and can be used to compute the clot ratio percentage which is in turn indicative of the platelet functionality. Any appropriate desired calculation may be made from the relative clotting times in each cell. The platelet functionality can in turn by utilized to determine blood loss during surgery and the need for a blood transfusion. The platelet functionality further assists in managing heparin therapy during cardiac surgery.

EXAMPLE I

PREPARATION OF PLATELET ACTIVATING FACTOR SOLUTIONS AND CELLS

1. Weigh out 62.5mg Bovine Serum Albumin (BSA) (Sigma Product #A-3803).
2. Weigh out 219mg NaCl.
3. Make up to 25ml with deionized water. This gives 0.25% BSA/0.15M NaCl. Leave until BSA is completely in solution.
4. Using a Hamilton syringe, pipette 50μl platelet activating factor 1-O-alkyl-2-acetyl-sn-glyceryl-3-phosphorylcholine into a clean stoppered vial and allow to evaporate in a fume hood. Add 2ml BSA/NaCl solution and leave at least 1 hour. This working stock material is at 100μM.
5. Dilute the working stock platelet activating factor (PAF) in tenths serially down to 0.1μM with deionized water. 5μl of each of these solutions gives 1.25μM, 12.5μM, 125μM and 1250μM in 0.4ml blood, respectively.
6. The following amounts are added to the cells and result in the indicated blood concentration:

Cell	Reagent Added	Concentration of PAF
A	5 μl BSA/NaCl	0 nM
B	5 μl 0.1 μM PAF	1.25 nM
C	5 μl 1 μM PAF	12.5 nM
D	5 μl 10 μM PAF	125 nM
E	2 μl 100 μM PAF	500 nM
F	5 μl 100 μM PAF	1250 nM

7. The water is allowed to evaporate, leaving a dry fill in each cell.
8. Using a sample of normal blood from a voluntary donor, and a cartridge prepared according to

EXAMPLE I, 0.4ml aliquots of blood were added to each cell and the clotting time of the blood in each cell was determined and plotted as Fig. 3.

As referred to above, the titration curve can be normalized by converting the clotting times to ratios. The clotting time of Cell A, with no platelet activating factor present, is the cell clotting time to which all other cell clotting times are compared. The ratio is calculated by dividing the Cell A clotting time in seconds by each other cell clotting time in seconds. A clot ratio is then calculated as 1 minus the ratio of Cell A clotting time to other cell clotting times (1 - cellAtime/cellxtime). Data can also be presented in terms of platelet function as a percentage of normal. This is calculated from the clot ratio by multiplying the clot ratio by 100 and then by a factor of 1.97 which has been determined by measuring the maximum platelet activating factor response in 22 normal donors. These donors had no known platelet disfunction and were taking no known medications.

The test cartridge and method described herein are useful for providing a simple and rapid response point-of-care platelet function assay. This assay identifies patients with excessive post-cardiopulmonary bypass blood loss who could benefit from further blood treatment and management.

While a certain illustrative embodiment of the present invention has been shown in the drawings and described above in detail, it should be understood that there is no intention to limit the invention to the specific form disclosed. On the contrary, the intention is to cover all modifications, alternative constructions and compositions, equivalents and uses falling within the

spirit and scope of the invention as expressed in the appended claims.

CLAIMS

1. Apparatus for evaluating platelet functionality of a blood sample, comprising a cartridge having a plurality of test cells, each said cell adapted for receiving an aliquot part of said sample, a measured amount of clotting reagent in each said cell, and a measured amount of platelet activation reagent in each said cell, the amount of such reagent in each said cell differing from the amount of such reagent in each other cell, whereby the relative clotting times of said samples in said cells are determinative of the platelet functionality of said sample.

2. An apparatus as defined in claim 1 wherein said platelet activation reagent is 1-O-alkyl-2-acetyl-sn-glyceryl-3-phosphorylcholine.

3. An apparatus as defined in claim 1 wherein said platelet activation reagent is selected from the group consisting of 1-O-alkyl-2-acetyl-sn-glyceryl-3-phosphorylcholine, collagen, epinephrine, ristocetin.

4. A method for determining platelet functionality in a blood sample comprising dividing said sample into a plurality of aliquot samples, performing a clotting test on each aliquot sample in the presence of a selected amount of a platelet activation reagent, the selected amount of platelet activation reagent for each aliquot sample being different one from another, and determining platelet functionality based on the difference in clotting times for each said aliquot sample.

5. A method as defined in claim 4 wherein said platelet activation reagent is 1-O-alkyl-2-acetyl-sn-glyceryl-3-phosphorylcholine.

6. A method as defined in claim 4 wherein said platelet activation reagent is selected from the group

consisting of 1-O-alkyl-2-acetyl-sn-glyceryl-3-phosphorylcholine, collagen, epinephrine, ristocetin.

7. Apparatus for evaluating clotting characteristics of a blood sample, comprising a cartridge having a plurality of test cells, each said cell adapted for receiving an aliquot of said sample, a measured amount of clotting reagent in each said cell, and a measured amount of a clotting affecting reagent in each said cell, the amount of such reagent in each said cell differing from the amount of such reagent in each other cell, whereby the relative clotting times of said samples in said cells are determinative of clotting characteristics of said sample.

8. A method for determining clotting characteristics of a blood sample, comprising dividing said sample into a plurality of aliquot samples, performing a clotting test on each aliquot sample in the presence of a selected amount of a clotting affecting reagent, the selected amount of reagent for each aliquot sample being different one from another, and determining clotting characteristics based on the difference in clotting times for each said aliquot sample.

9. An apparatus as defined in claim 7 wherein said clotting affecting reagent is a platelet activator.

10. A method as defined in claim 8 wherein said clotting affecting reagent is a platelet activator.

TEST CARTRIDGE FOR EVALUATING BLOOD PLATELET FUNCTIONALITY

ABSTRACT

Apparatus and method for evaluating platelet functionality of a blood sample. A cartridge includes a plurality of test cells. Each cell receives an aliquot part of a blood sample. A measured amount of clotting reagent is provided in each cell. A measured amount of platelet activation reagent is provided in each cell, the amount of such reagent in each cell differing from the amount of such reagent in each other cell. The relative clotting times of the aliquot samples in the cells are determinative of the platelet functionality of the blood sample.

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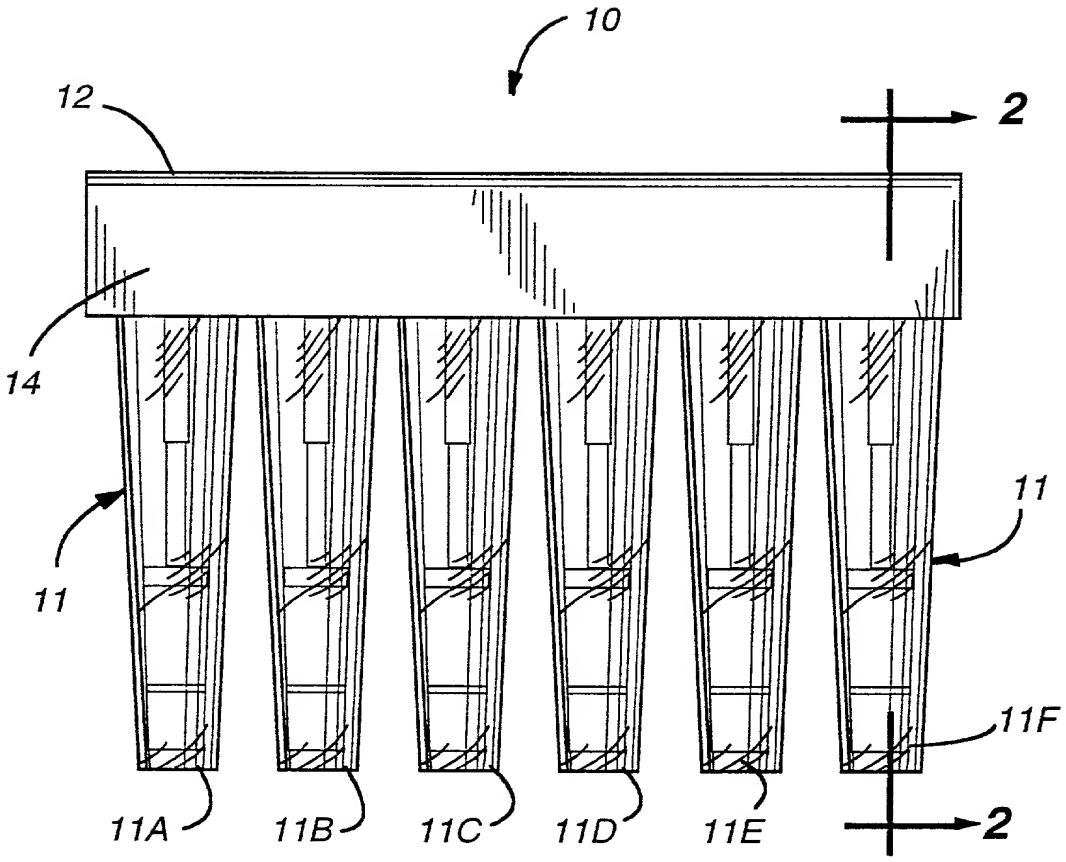

Fig. 1

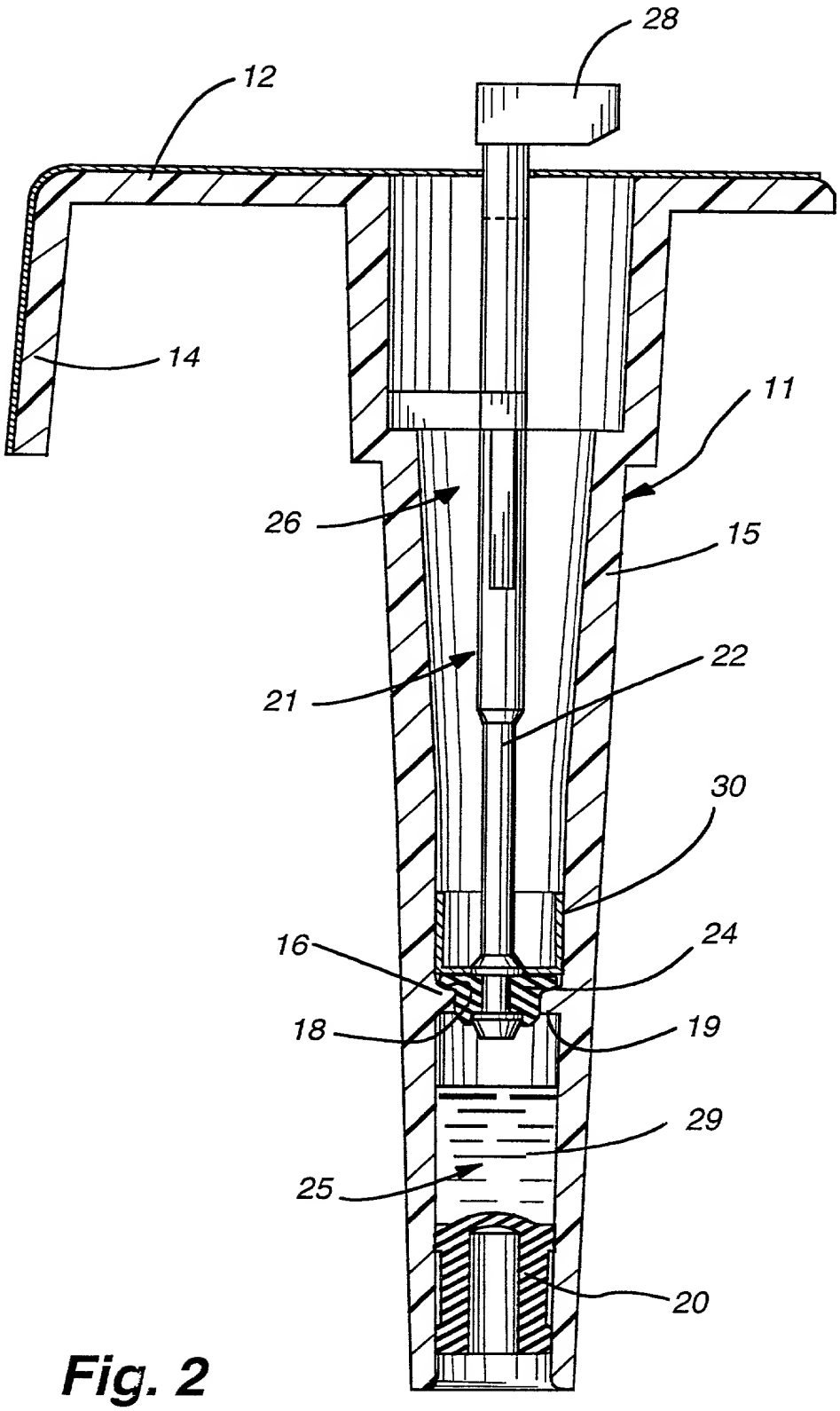

Fig. 2

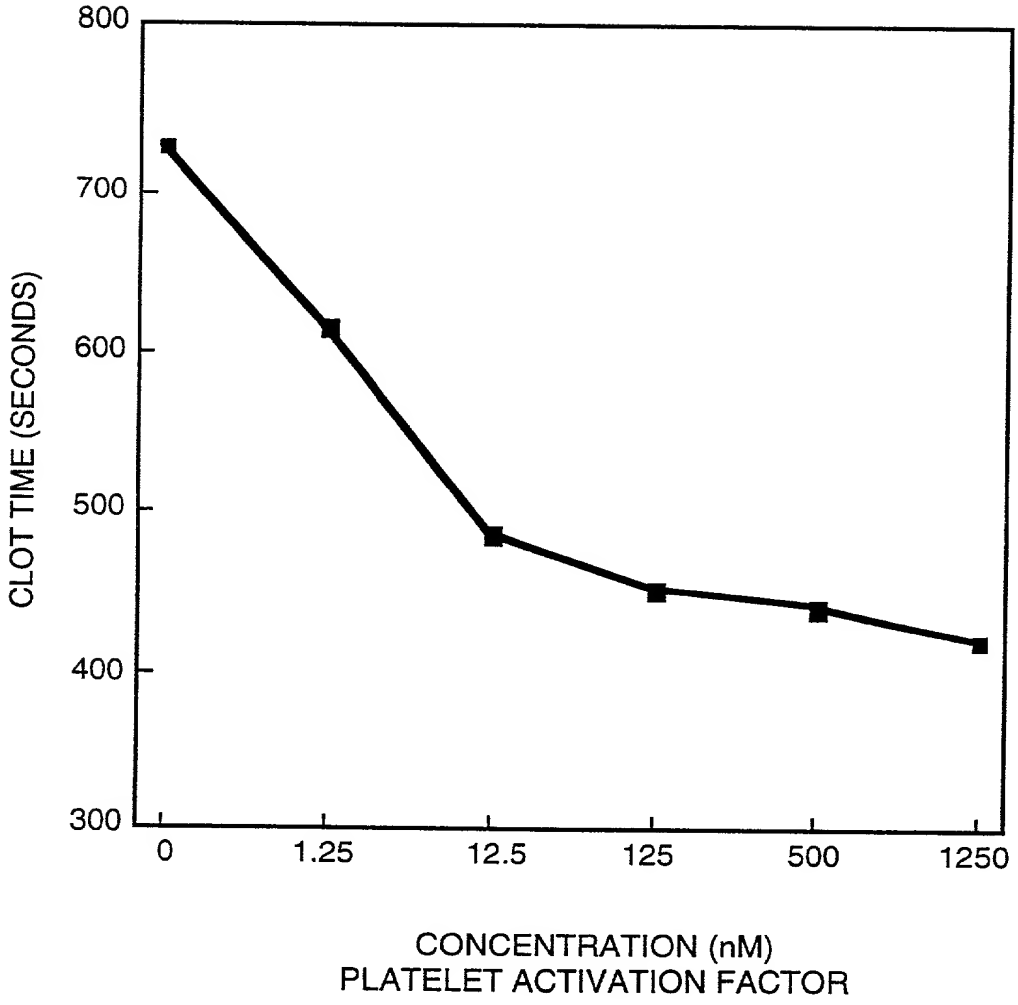
800
700
600
500
400
300
CLOT TIME (SECONDS)
0
1.25
12.5
125
500
1250
CONCENTRATION (nM)
PLATELET ACTIVATION FACTOR

Fig. 3

Attorney's Docket No. 16353.830006 **PATENT**

COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL, CONTINUATION OR C-I-P)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type:

(check one applicable item below)

- ☒ original.
- ☐ design.
- ☐ supplemental.

NOTE. If the declaration is for an International Application being filed as a divisional, continuation or continuation-in-part application, do not check next item; check appropriate one of last three items.

- ☐ national stage of PCT.

NOTE. If one of the following 3 items apply, then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION OR C-I-P.

- ☐ divisional.
- ☐ continuation.
- ☐ continuation-in-part (C-I-P).

INVENTORSHIP IDENTIFICATION

WARNING: *If the inventors are each not the inventors of all the claims, an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.*

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am the original, first and sole inventor *(if only one name is listed below)* or an original, first and joint inventor *(if plural names are listed below)* of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

TITLE OF INVENTION

TEST CARTRIDGE FOR EVALUATING BLOOD PLATELET FUNCTIONALITY

SPECIFICATION IDENTIFICATION

the specification of which:

(complete (a), (b) or (c))

(a) ☐ is attached hereto.

(b) ☒ was filed on Apr. 30, 1996 as ☒ Serial No. 08/ 640,275
or ☐ Express Mail No., as Serial No. not yet known _____
and was amended on _____ *(if applicable)*.

NOTE: Amendments filed after the original papers are deposited with the PTO that contain new matter are not accorded a filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 CFR 1.67.

(c) ☐ was described and claimed in PCT International Application No. _____ filed on _____ and as amended under PCT Article 19 on _____ *(if any)*.

ACKNOWLEDGEMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information, which is material to patentability as defined in 37, Code of Federal Regulations, § 1.56.

(also check the following items, if desired)

☒ and which is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable Examiner would consider it important in deciding whether to allow the application to issue as a patent, and

☐ in compliance with this duty, there is attached an information disclosure statement, in accordance with 37 CFR 1.98.

PRIORITY CLAIM (35 U.S.C. § 119(a)-(d))

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(complete (d) or (e))

(d) ☒ no such applications have been filed.

(e) ☐ such applications have been filed as follows.

NOTE: Where item (c) is entered above and the International Application which designated the U.S. itself claimed priority check item (e), enter the details below and make the priority claim.

PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. § 119(a)-(d)

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING (day, **month**, year)	PRIORITY CLAIMED UNDER 37 USC 119
			☐ YES NO ☐
			☐ YES NO ☐
			☐ YES NO ☐
			☐ YES NO ☐
			☐ YES NO ☐

CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S)

(34 U.S.C. § 119(e))

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

PROVISIONAL APPLICATION NUMBER	FILING DATE
_____ /_____	_____
_____ /_____	_____
_____ /_____	_____

CLAIM FOR BENEFIT OF EARLIER US/PCT APPLICATION(S) UNDER 35 U.S.C. 120

☐ The claim for the benefit of any such applications are set forth in the attached ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR CONTINUATION-IN PART (C-I-P) APPLICATION.

ALL FOREIGN APPLICATION(S), *IF ANY*, FILED MORE THAN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

_____

_____

_____

NOTE: If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR C-I-P APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. § 120.

POWER OF ATTORNEY

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

(list name and registration number)

Richard A. Bachand #25,107	Homer L. Knearl #21,197
Carol W. Burton #35,465	William J. Kubida #29,664
William C. Cochran #26,652	Lee R. Osman #38,260
Angus C. Fox, III #31,828	F. A. Sirr #17,265
Earl C. Hancock #19,472	John R. Wahl #33,044

(check the following item, if applicable)

☐ Attached, as part of this declaration and power of attorney, is the authorization of the above-named attorney(s) to accept and follow instructions from my representative(s).

SEND CORRESPONDENCE TO

Lee R. Osman
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DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

NOTE: Carefully indicate the family (or last) name, as it should appear on the filing receipt and all other documents.

Full name of sole or first inventor

Robert (GIVEN NAME) F. (MIDDLE INITIAL OR NAME) Baugh (FAMILY (OR LAST NAME))

Inventor's signature Robert F Baugh

Date 7/2/96 **Country of Citizenship** U.S.A.

Residence 7926 East Windcrest Row, Parker, Colorado 80134

Post Office Address 7926 East Windcrest Row, Parker, CO 80134

Full name of second joint inventor, if any

Carole (GIVEN NAME) G. (MIDDLE INITIAL OR NAME) Lane (FAMILY (OR LAST NAME))

Inventor's signature Carole G Lane

Date 7/2/96 **Country of Citizenship** U.S.A.

Residence 9155 East Stanford Place, Greenwood Village, CO 80111

Post Office Address 9155 East Stanford Place, Greenwood Village, CO 80111

Full name of third joint inventor, if any

Adrian (GIVEN NAME) C. (MIDDLE INITIAL OR NAME) Wilson (FAMILY (OR LAST NAME))

Inventor's signature Adrian C. Wilson

Date 7/2/96 **Country of Citizenship** ~~U.S.A.~~ UK ATW 7/2/96

Residence 1585 Krameria Street, Denver, Colorado 80220-1550

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(check proper box(es) for any of the following added page(s) that form a part of this declaration)

☐ **Signature** for fourth and subsequent joint inventors. *Number of pages added* _____.

• • •

☐ **Signature** by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor. *Number of pages added* _____.

• • •

☐ **Signature** for inventor who refuses to sign or cannot be reached by person authorized under 37 CFR 1.47. *Number of pages added* _____

• • •

☐ Added page for **signature** by one joint inventor on behalf of deceased inventor(s) where legal representative cannot be appointed in time. (37 CFR 1.47)

• • •

☐ Added pages to combined declaration and power of attorney for divisional, continuation, or continuation-in-part (C-I-P) application.

☐ Number of pages added _____

• • •

☐ Authorization of attorney(s) to accept and follow instructions from representative.

• • •

(if no further pages form a part of this Declaration, then end this Declaration with this page and check the following item)

☒ This declaration ends with this page.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	Robert F. Baugh Carole G. Lane Adrian C. Wilson	)))
		)Examiner: NOT YET ACCORDED
Serial No:	08/640,275	)
Filing Date:	04/30/96	)Art Unit: 1313
Title:	Test Cartridge for Evaluating Blood Platelet Functionality	))
Att'y Dkt No:	17720-1/P4455	)

INTERVENTION BY ASSIGNEE,
REVOCATION OF POWER OF ATTORNEY
AND
APPOINTMENT OF NEW POWER OF ATTORNEY

To: Assistant Commissioner of Patents and Trademarks
BOX NO FEE
Washington, D.C. 20231

Sir:

Medtronic, Inc., a corporation organized and existing under the laws of the State of Minnesota, and the assignee of record of the entire right, title and interest in and to the above-referenced patent application, **hereby intervenes** in this patent application and **revokes all powers of attorney** previously appointed by the inventors or by any other entity in this patent application.

Medtronic, Inc., hereby appoints, effective immediately, as principle attorneys James R. Young, Registration No. 27,847; Steven C. Petersen, Registration No. 36,238; Robert G.

Crouch, Registration No. 34,806; Scott Allison, Registration No. 38,370; and Barbara A. Gyure, Registration No. 34,614, all of the law firm of Chrisman, Bynum and Johnson, P.C.; and Harold R. Patton, Reg. No. 22,157; Reed A. Duthler, Reg. No. 30,626; Daniel W. Latham, Reg. No. 30,401; Michael B. Atlass, Reg. No. 30,606; Peter Forrest, Reg. No. 33,235; Dianne M.F. Plunkett, Reg. No. 35,649; Michael A. Jaro, Reg. No. 34,472; Curtis D. Kinghorn, Reg. No. 33,926; and Thomas F. Woods, Reg. No. 36,726, all employees of Medtronic, Inc., a Minnesota corporation, as our attorneys, respectively, to prosecute the above-referenced patent application and to transact all business in the United States Patent and Trademark Office connected therewith.

Please direct all correspondence relating to this patent application to:

Steven C. Petersen, Esq.
CHRISMAN, BYNUM & JOHNSON, P.C.
1900 Fifteenth Street
Boulder, CO 80302
Tel: (303) 546-1300

MEDTRONIC, INC.

Harold R. Patton,
Vice President and Chief Patent Counsel

Date: April 2, 1997